No. 17-290

IN THE

# Supreme Court of the United States

MERCK SHARP & DOHME CORP.,
*Petitioner,*

v.

DORIS ALBRECHT, ET AL.,
*Respondents.*

On Writ of Certiorari to the
United States Court of Appeals for the Third Circuit

## BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF RESPONDENTS

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## INTEREST OF AMICUS CURIAE[1]

Public Citizen is a non-profit consumer advocacy organization with members and supporters in every state. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and advocated before the Food and Drug Administration (FDA) for product labeling and regulation to reduce safety risks. In June 2013, a Public Citizen report compiled a list of drugs for which black-box warnings—the most serious contraindications and warnings—were added after a generic equivalent entered the market. Looking at a five-year period, the report identified 53 drugs for which a black-box warning calling attention to serious or life-threatening risks was added after generic market entry. The data underscore the public health imperative of requiring pharmaceutical companies to maintain active surveillance of safety.

In both this Court and the lower courts, Public Citizen has participated as amicus in many cases brought by patients injured by drugs that carried inadequate warnings. Patients and physicians depend on brand-name manufacturers to provide adequate warnings for prescription drugs. Allowing patients to pursue tort claims against pharmaceutical manufacturers for injuries caused by inadequate warnings is important as both an incentive for manufacturers to be vigilant about product safety and a means to provide remedies to patients. For this reason, this case has important implications that go well beyond the interests of the parties.

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[1] This brief was not authored in whole or part by counsel for a party. No one other than amicus curiae Public Citizen made a monetary contribution to preparation or submission of the brief. Counsel for all parties have consented in writing to the filing of this brief through blanket consents on file with the Court.

## SUMMARY OF ARGUMENT

I. The Food, Drug, and Cosmetic Act (FDCA), as this Court has explained, was enacted "to bolster consumer protection against harmful products." *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (citing *Kordel v. United States*, 335 U.S. 345, 349 (1948), and *United States v. Sullivan*, 332 U.S. 689, 696 (1948)). When enacting this consumer protection law, however, Congress did not create a federal remedy for consumers harmed by unsafe or ineffective drugs. To the contrary, Congress rejected a provision that would have created a damages remedy, *see* H.R. 6110, 73d Cong., 1st Sess. § 25 (1933), specifically because state law already provided one, *see Wyeth*, 555 U.S. at 574 & n.7. Indeed, "[c]ourts entertained tort suits against [drug] manufacturers since well before the passage" of the FDCA, and such litigation has long been a "common feature of the legal landscape." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 441 (2005) (discussing pesticides).

Against this background and the principles established by this Court's preemption jurisprudence, *Wyeth* provides a clear framework for deciding this case. Federal regulations task a brand-name drug manufacturer with primary responsibility for keeping its product labeling up to date, and they provide the manufacturer with the flexibility to do so. Here, Merck did not update its labeling until ordered to do so by the FDA, years after Merck became aware of evidence that Fosamax was associated with a risk of atypical femoral fractures. Under *Wyeth*, Merck cannot bear the burden of showing that, had Merck added a warning about atypical femoral fractures before 2010, the FDA would have rejected the updated warning of this risk—known to physicians as "Fosamax fractures." JA448.

**II.** Merck and its amicus curiae PhRMA, however, suggest that the Food and Drug Administration Amendments Act of 2007 (FDAAA) altered the regulatory scheme under which this Court decided *Wyeth*. In fact, the 2007 law reinforced *Wyeth*'s central premise: that prescription drug manufacturers have primary responsibility for keeping drug labeling updated and that, therefore, "absent clear evidence that the FDA would not have approved a change" to the drug's label, the Court "will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571.

Notwithstanding that most labeling changes are initiated by manufacturers, Merck and PhRMA argue that the Court should infer here the FDA would not have permitted any update to the Warnings or Precautions sections to advise physicians and patients about atypical femoral fractures. They argue that, under the FDAAA, the FDA is required to order labeling changes where warranted and, thus, if the FDA has not ordered a change, none was warranted. As applied to the facts here, their theory is that, when the FDA did not approve the *stress* fracture warning proposed in 2009, it signaled that no warning concerning *atypical* fractures would be permitted. The theory is illogical, speculative, and undercut by the facts of this case.

**III.** State law has long recognized that federal regulation has a role in products liability cases, because compliance with federal regulation is relevant to establish whether the manufacturer acted reasonably. Regulatory compliance is both a strong defense to a state-law tort claim and a reflection of the fact that juries have long been charged with considering the actions of federal regulators, including the FDA. This case presents no

ground for shifting the longstanding role of factfinders in deciding factual disputes underlying legal claims and defenses.

## ARGUMENT

### I. The standard stated by this Court in *Wyeth* governs the preemption analysis here.

**A.** Consideration of preemption of state-law claims seeking damages for injuries caused by prescription drugs begins with this Court's decision in *Wyeth*. And understanding of *Wyeth* begins with the longstanding "cornerstones of [the Court's] pre-emption jurisprudence." *Wyeth*, 555 U.S. at 565.

> First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted); *see Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " *Lohr*, 518 U.S., at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

*Wyeth*, 555, U.S. at 565.

Because the cornerstones are familiar, it is easy to skip over them. The Court has reiterated them time and again, however, because they embody important principles of the Nation's federal scheme: As Justice Thomas wrote in *Wyeth*, "to ensure the protection of our fundamental liberties, the Constitution establishes a system of dual

sovereignty between the States and the Federal Government." *Id.* at 583–84 (Thomas, J., concurring in the judgment) (quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985) (internal quotation marks omitted), and *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991) (internal quotation makers omitted)). The States are "independent sovereigns in our federal system." *Id.* at 566 n.3 (majority opinion). Thus, "in protecting our constitutional government, 'the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government.'" *Id.* at 585 (Thomas, J., concurring) (quoting *Texas v. White*, 7 U.S. 700, 725 (1868)).

The preemption touchstones—Congress's legislative purpose and the presumption against preemption—thus derive from core constitutional principles. Accordingly, out of respect for the states' sovereignty and their traditional role in protecting the health and safety of their citizens, the Court assumes that "Congress does not cavalierly pre-empt state-law causes of action." *Lohr*, 518 U.S. at 485.

**B.** Although the drug provisions of the FDCA have been amended many times since 1938, including significant amendments in 1962, 1984, 1997, 2007, and 2012, arguments that products liability suits (whether based on design or labeling) against drug manufacturers were preempted by the FDCA were seldom made and, until the mid-2000s, rarely successful.[2] Significantly, in

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[2] *See, e.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537 (6th Cir. 1993) (no preemption); *Osburn v. Anchor Labs.*, 825 F.2d 908, 911–13 (5th Cir. 1987) (same); *Wells v. Ortho Pharm. Corp.*, 788

1962, when Congress amended the FDCA to require, for the first time, that drug manufacturers demonstrate effectiveness in addition to safety prior to receiving marketing approval, *see Wyeth*, 555 U.S. at 567, Congress addressed preemption only to state that the new provisions do *not* preempt state law.[3]

Later, beginning in 1976, Congress enacted provisions expressly preempting categories of state laws with respect to other FDA-regulated products, including foods, medical devices, and cosmetics. *See* 21 U.S.C. §§ 343-1(a), 360k(a), & 379s. As these preemption provisions reflect, Congress has been particularly attentive to federalism concerns in connection with regulation under the FDCA and has crafted provisions to address these concerns where, in Congress's view, those changes were appropriate. Yet Congress never enacted a provision preempting state law concerning prescription drugs, much less a provision directed at state-law damages suits.

Against this backdrop, and the Court's longstanding touchstones of preemption analysis, the Court in *Wyeth* rejected the notion that "obstacle" conflict preemption bars state-law claims brought against brand-name drug manufacturers for injuries caused by inadequate labeling of their products. 555 U.S. at 573; *id.* at 604 (Thomas, J., concurring in the judgment) (rejecting notion of obstacle

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F.2d 741, 746 (11th Cir. 1986) (same); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1195–97 (N.J. 1991) (same).

[3] *See* Pub. L. No. 87-781, § 202 (1962) ("Nothing in the amendments made by this Act to the federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.").

preemption). At the same time, while not ruling out the possibility that "impossibility" conflict preemption might apply in some instances, the Court held that the manufacturer had failed to carry its burden of establishing impossibility in that case. *Id.* at 571; *see also id.* at 593 (Thomas, J., concurring).

*Wyeth*'s holding with respect to impossibility preemption of a state-law claim based on the failure to provide an adequate warning in drug labeling is straightforward: "[A]bsent clear evidence that the FDA would not have approved a change to [the] label" to include the warning, the Court "will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Id.* at 572. And absent an "affirmative decision" by the FDA, such clear evidence is lacking. *Id.* at 571.

This approach follows directly from the regulatory scheme. Since 1938, the manufacturer of a new prescription drug must obtain prior approval from the FDA before the drug can be marketed, including approval of each use for which the manufacturer intends to market it. As the parties' briefs explain, to obtain marketing approval, a drug company must first submit a new drug application (NDA) for the FDA's review. 21 U.S.C. § 355(a), (b). If, after reviewing the application, the FDA concludes that the drug is safe and effective for its intended use or uses and that the labeling is not false or misleading, the FDA will send an approval letter to the applicant. *Id.* §§ 355(c)(1)(A), 355(d). FDA approval includes approval of the labeling, which must include several sections, including contraindications, warnings, precautions, and adverse reactions. 21 C.F.R. §§ 201.56, 201.57, 201.80.

Nonetheless, "[m]any serious [adverse drug reactions] are discovered only after a drug has been on the market

for years." Karen Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (May 1, 2002); *see* Jean Lester, et al., *Evaluation of FDA safety-related drug label changes in 2010*, 22 Pharmacoepidemiology and Drug Safety 302, 304 (2013) (stating that "[t]he most critical safety-related label changes" were made "a median 10 and 13 years after drug approval"). To monitor adverse reactions, the FDA requires companies to submit "adverse event reports" to the agency, describing both "serious and unexpected" reactions and less serious ones. *See* 21 C.F.R. § 314.80(c)(1), (2). In this way, federal regulations put the onus of postmarketing surveillance on drug manufacturers, not on the FDA.

In addition, as *Wyeth* discussed, federal regulations impose on manufacturers a continuing responsibility "to maintain their labeling and update the labeling with new safety information." 73 Fed. Reg. 49603, 49605 (Aug. 22, 2008); *see Wyeth*, 555 U.S. at 570–71. A manufacturer can make certain post-approval labeling changes only with prior FDA approval, 21 C.F.R. § 314.70(b), but no prior approval is required for changes "[t]o add or strengthen a contra-indication, warning, precaution, or adverse reaction," *id.* § 314.70(c)(6)(iii), among other things, *id.* §§ 314.70(c), (d). A company's obligation to provide physicians and patients with up-to-date warnings and precautions continues as long as the product is marketed. 21 C.F.R. §§ 201.57(c)(6), 201.80(e). As *Wyeth* noted, "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." 555 U.S. at 1202; *see also, e.g.*, *id.* at 1202 n.11 (citing studies showing that FDA resources are inadequate to its regulatory responsibilities).

In light of the regulatory scheme, and reinforced by the reality that manufacturers initiate the majority of labeling updates, this Court held in *Wyeth* that FDA approval of prescription drug labeling does not immunize a brand-name drug manufacturer from liability for failure to warn. Rather, absent a clear showing that the FDA would not allow a warning that state law requires, compliance with both federal and state law is not impossible, and federal regulation does not preempt patients' state-law claims.

Merck has not made that showing here.

## II. The Food and Drug Administration Amendments Act of 2007 does not alter the preemption analysis.

Petitioner Merck and its amicus curiae PhRMA argue that, in light of the FDAAA, the FDA's rejection of a particular manufacturer-suggested labeling change necessarily connotes the FDA's "considered judgment" that *no* change should be made at all. PhRMA Br. 4. In *Wyeth*, this Court considered and rejected a similar argument that regulation under the FDCA—including the FDCA as amended by the FDAAA—establishes both a floor and a ceiling for drug regulation. As the Court said at that time, "[t]he most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary." *Wyeth*, 555 U.S. at 574.

**A.** *Wyeth* considered and addressed the effect of the FDAAA on analysis of federal preemption of state-law labeling claims, which was enacted after the relevant events in *Wyeth* but before the Court decided *Wyeth*. As the Court's opinion makes clear, the FDAAA did not alter the essential premises that underlie its holding: manufacturers' responsibility for labeling and their authority to make changes without prior approval.

The FDAAA gave the FDA additional resources for drug safety and new authority to compel manufacturers to make labeling changes based on safety information that becomes available after a drug's initial approval. *See* 21 U.S.C. § 355(o)(4)(A). Nonetheless, "the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA." 153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (Statement of Sen. Kennedy). Indeed, "no matter what [Congress does], they will always have vastly greater resources to monitor the safety of their products than the FDA does." *Id.* Not surprisingly, therefore, even *after* passage of the FDAAA in 2007, the majority of revisions to the "Warnings" and "Precautions" sections of prescription drug labeling are initiated by manufacturers, not by the FDA. *See* Lester, *supra*, at 304 (discussing labeling changes made in 2010).

Consistent with these facts, and as *Wyeth* explains, when Congress in 2007 "granted the FDA this authority [to order labeling changes], it reaffirmed the manufacturer's obligations and referred specifically to the "changes being effected" regulation, 21 C.F.R. § 314.70(c), "which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval," *Wyeth*, 555 U.S. at 571. In addition, as *Wyeth* also explains, Congress rejected a proposed provision "that would have required the FDA to preapprove all changes to drug labels" and instead "adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels." *Wyeth*, 555 U.S. at 567–68 (citing Senate bill and provision now codified at 21 U.S.C. § 355(o)(4)(I)); *see* 21 U.S.C. § 355(o)(4)(I) (stating that the authority granted to the FDA to initiate labeling changes "shall not be construed to affect the responsibility of the [manufacturer] to maintain its label

in accordance with existing requirements, including ... [21 C.F.R. §] 314.70").

In short, this Court in *Wyeth* both considered and addressed the impact of the FDAAA on preemption of state-law claims, and it correctly rejected the argument that the FDAAA alters the preemption analysis.

**B.** Merck and its amicus curiae PhRMA suggest that the provision of the FDAAA that grants the FDA authority to require labeling changes when new information is brought to its attention alters the underpinning of *Wyeth*, at least in the circumstances of this case. Under their theory, the FDAAA requires the FDA to order any labeling change that it deems required by available information, and, therefore, when the FDA rejects a proposed labeling change on a topic, it is necessarily rejecting any other change that the manufacturer could have proposed at that time. That argument is not a reasonable construction of the statute.

Nothing in the FDAAA requires the FDA, when presented with a proposed labeling change, to consider any changes other than those proposed to it. And nothing in the FDAAA suggests that an FDA response, when it does not propose a warning of its own, necessarily indicates that the agency has considered and rejected any warning other than the one proposed by the manufacturer. The statute thus does not support the notion that the FDA's rejection of a particular proposed warning constitutes a determination "that no new labeling language is warranted." PhRMA Br. 17. This point is true in particular where the FDA states that the specific proposed change is not supported by "the available literature and postmarketing adverse event reporting," JA511–12, but a manufacturer knows that the literature and reports would support a different proposal. *See* Resp.

Br. 9–10 (describing record evidence of Merck's knowledge of adverse events and studies).

Moreover, tasking the FDA with anticipating and considering all possible labeling changes that might be proposed when it accepts or rejects a particular change proposed by a manufacturer would be impractical. Consistent with the facts as they existed pre-FDAAA, *see Wyeth*, 555 U.S. at 578–79 & n.11, a 2015 report of the Government Accountability Office (GAO) found that the "FDA's lack of reliable, readily accessible postmarket safety data has prevented the agency from publishing required reports in a timely manner and has restricted its ability to conduct systematic oversight." GAO, Drug Safety: FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement 22, https://www.gao.gov/assets/680/674183.pdf (Dec. 2015). Further, GAO estimated that the FDA failed to review in a timely manner more than half of the submissions associated with 1,400 postmarket studies of drugs on the market. *Id.* at 23–24.

The FDA, too, recognizes the need for continued reliance on manufacturers to identify hazards and initiate labeling changes. As the FDA advised manufacturers several years after passage of the FDAAA, the agency "does not anticipate that all labeling changes that may be related to safety will be required and reviewed under" the authority granted it by FDAAA. FDA, *Guidance for Industry Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act* 5 (July 2013), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM250783.pdf. Instead, manufacturers are expected to continue to submit labeling revisions "using standard procedures." *Id.*

Thus, the FDAAA does not alter the preemption analysis. Both before the FDAAA and after, the preemption question, as articulated by this Court, is whether there is "clear evidence that the FDA would not have approved a change" to the drug labeling that a plaintiff alleges was inadequate. *Wyeth*, 555 U.S. at 571. Merck's and (more explicitly) PhRMA's suggestion that the FDA's rejection of one specific proposed warning represents a determination that no new warning was permissible is unsupported by the FDAAA and divorced from the reality of prescription drug labeling and FDA practice.

C. Because the FDAAA does not support the notion that the FDA's rejection of one warning connotes, as a matter of law, a rejection of a substantively different warning, the FDA's rejection of a particular warning subsequent to enactment of the FDAAA presents the same questions that this Court in *Wyeth* held controlled preemption under the FDCA: Does the FDA's action clearly demonstrate that the agency rejected or would have rejected the warning that the plaintiff says that state law requires? Under the circumstances here, the FDA's action cannot be so understood.

As respondents have explained, atypical femoral fractures and stress fractures are distinct; the terms denoting the two types of fractures are neither synonyms nor two ways of describing a similar injury. *See* Resp. Br. 12–13. When the FDA rejected the proposed stress fracture warning in May 2009, it explained that "[d]iscussion of the risk factors for *stress* fractures is not warranted and is not adequately supported by the available literature and postmarketing adverse event reporting." JA511–12 (emphasis added). At the same time, the agency approved a labeling revision to add "low

energy femoral shaft and subtrochanteric fractures" (atypical femoral fractures) to the Adverse Reactions section, JA512—meaning that it found a "basis to believe" that there is a "causal relationship" between Fosamax and those atypical fractures. *See* 21 C.F.R. § 201.57(c)(7).

The FDA's 2009 letter belies Merck's claim that the FDA was rejecting a proposed warning—or any warning—about the risk of atypical femoral fractures. The relevant sentence says that, while the FDA "agrees" that "atypical and subtrochanteric fractures" should be added to the Adverse Reactions section of the labeling, "[Merck's] justification for the proposed Precautions section language is inadequate." Quoting Merck's proposed Precaution language, the FDA explains: "Identification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature." JA511. That is, the FDA was rejecting a warning *about stress fractures* because the evidence of *atypical* fractures shown in the literature did not support it. The letter, which explicitly distinguishes between atypical and stress fractures, offers no support for the notion that the FDA was rejecting an atypical fracture warning, much less that it was rejecting any possible atypical fracture warning.

In addition, Merck's position overlooks that the FDA wrote to Merck in 2008 that it was "aware of reports" that patients were suffering atypical femoral fractures and was "concerned about this developing safety signal," JA280—a position in tension with Merck's view that the FDA in 2009 had in mind atypical femoral fractures when it rejected the proposed warning on the ground that

discussion of stress fractures was "not adequately supported" by "adverse event reporting," JA511–12.[4]

The FDAAA does not require the assumption of such FDA incoherence, particularly in the face of an entirely logical alternative. As the FDA explained in rejecting Merck's second attempt to warn of stress fractures rather than the more serious atypical femoral fractures, "for most practitioners, the term 'stress fracture' represents a minor fracture and this would contradict the seriousness of the atypical femoral fractures associated with" use of Fosamax. JA566. This FDA response again shows that the agency's rejection in 2009 of the proposed warning about stress fractures cannot reasonably be deemed "clear evidence that the FDA would not have approved" a warning to address atypical femoral fractures—a warning that Merck could have, but never, proposed.

Reinforcing that the FDA's May 2009 rejection of the proposed stress fracture warning did not represent a determination that a possible warning or precaution about atypical femoral fractures was not warranted, the FDA suggested to Merck in April 2009 that Merck forgo further discussion of the warning it had proposed and then work with FDA "to decide on language for a W&P [Warning & Precaution] atypical fracture language, if it is warranted." JA508. The FDA suggested that warning language for atypical fractures could be agreed on soon. *See id.* (stating that the FDA was "hopeful" of agreeing on

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[4] That the FDA was addressing Merck's proposed warning for stress fractures, not a possible warning for atypical femoral fractures that had not been proposed, when it rejected Merck's language as "not adequately supported by the available literature and postmarketing adverse event reporting" is further supported by the fact that "[b]etween 1995 and 2010, scores of case studies, reports, and articles were published documenting possible connections between long-term bisphosphonate use and atypical femoral fractures." Pet. App. 13a.

language "in time to allow that language to be included in the PLR [Physician Labeling Rule] conversion supplement"); JA767 (memo from Merck employee stating that FDA "reminded me that we also need to respond to their request for PLR by June"). These materials are incompatible with the notion that a court could decide, as a matter of law, that the FDA would not permit a warning or precaution concerning atypical femoral fractures.[5]

"The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). In this case, Merck failed to suggest an atypical femoral fracture warning, and Merck's and the FDA's correspondence about a stress fracture warning cannot reasonably be deemed "clear evidence" that Merck could not warn about the risk of atypical femoral fractures. Accordingly, under this Court's precedents, the patients' state-law claims are not preempted.

## III. Where factual disputes exist, juries in tort actions have long been tasked with considering the actions of regulators.

Here, the regulatory record fails as a matter of law to support Merck's claim of impossibility preemption. To the extent that a preemption defense turned on disputes of material fact, however, the Solicitor General's concern that juries would not be qualified to resolve those factual issues, *see* Br. of U.S. at 18–21, is unwarranted.

To begin with, juries have long been charged with evaluating agency actions in the context of tort suits.

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[5] The PLR conversion supplement is the means for revising older labeling to bring it into compliance with a 2006 FDA rule that set forth new requirements for drug labeling.

Under traditional tort law, federal approval of a product for marketing and a manufacturer's compliance with federal requirements for product safety plays a role, often a very powerful role, in products liability cases. Consistent with this tradition, the current law in most states allows a manufacturer that is alleged to have sold a defective product to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently. *See Restatement (Third) of Torts* § 4(b) (1998); *accord* 63B Am. Jur. 2d *Prods. Liab.* § 1922 (Nov. 2018 update) ("As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case.").[6] As the New Jersey Supreme Court recently put it, "federal regulations are of the utmost significance in determining whether 'a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product.'" *In re Accutane Litig.*, __ A.3d __, 2018 WL 4761403, at *25 (N.J. 2018) (quoting *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999)).

Thus, in New Jersey, for example, state law provides manufacturers with the protection of a *rebuttable* presumption of adequacy of an FDA-approved label

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[6] *See, e.g.*, Ind. Code § 34-20-5-1; Kan. Civ. P. Code Ann. § 60-3304; Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78B-6-703(2); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); *O'Neill v. Novartis Consumer Health, Inc.*, 55 Cal. Rptr. 3d 551, 557 (Cal. Ct. App. 2007); *Wagner v. Clark Equip. Co.*, 700 A.2d 38, 50 (Conn. 1997); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995); *Zacher v. Budd Co.*, 396 N.W.2d 122, 133–34 (S.D. 1986); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70–71 (Mass. 1985); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1039–40 (Ill. App. Ct. 1984); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143–44 (N.Y. App. Div. 1967).

warning. *Id.* (citing N.J. Stat. Ann. 2A:58C-4). "A manufacturer that acts in a reasonable and timely way to update its label warnings with the FDA, in accordance with its federal regulatory responsibilities, will receive the protection of the rebuttable presumption." *Id.* at *26.

Although this aspect of state-law claims goes to the merits, not to preemption, it is pertinent here. States have long recognized the importance of the federal regulatory scheme in assessing the reasonableness of conduct alleged to violate state tort law. And in assessing whether a regulatory compliance defense is meritorious, juries have long been charged with considering the connection between a defendant's conduct, federal regulation, and the regulator's decisions.

In addition, the FDCA itself expressly confers on juries the role of factfinder in civil cases stemming from FDA enforcement actions seeking injunctions for violations of the statute, or for seizure of misbranded or adulterated items, *see* 21 U.S.C. §§ 332(b), 334(b), as well as in criminal prosecutions for violations of the FDCA, *id.* § 333 (providing for criminal penalties); *see also Wyeth*, 555 U.S. at 570 ("the statute contemplates that federal juries will resolve most misbranding claims").

Where factual issues are disputed, our legal tradition tasks juries with resolving them. "This is not a rule specific to [a particular legal issue]; it is simply an application of the more general rule that a 'judge's function' at summary judgment is not 'to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.'" *Tolan v. Cotton*, 572 U.S. 650, 656 (2014) (discussing qualified immunity; quoting *Anderson v., Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). *See, e.g., Ortiz v. Jordan*, 562 U.S. 180 (2011) (although qualified immunity is

generally a question of law, case proceeded to a jury where the defense turned on disputed issues of fact).

No reasoned basis exists for a special rule requiring judges exclusively to take on the role of factfinder for factual disputes that arise in considering a preemption defense. *See Boyle v. United Technologies Corp.*, 487 U.S. 500, 514 (1988) ("whether the facts establish the conditions for the defense is a question for the jury").

## CONCLUSION

For the foregoing reasons and the reasons stated in the brief of respondents, the decision below should be affirmed.

Respectfully submitted,

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